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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Steven R. Bailey

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

NOTIFICATION DATE

DELIVERY MODE

09/17/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@biopatentlaw.com

Office Action Summary	Application No. 09/783,633	Applicant(s) BAILEY ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 68-76 have been considered but are moot in view of the new ground(s) of rejection. The Santini (US 2004/0260391 A1) and Burmeister (EP 0 759 730 B1) rejections have been maintained and the new interpretation of the references is outlined below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is indefinite. Line 13 requires the geometry change to change the position of the structural elements relative the geometry of the second material. This is rendered indefinite for two reasons. It is unclear how the geometry of the second material can change. That is, how can a "material" change geometry. It seems applicant intended to claim the geometry of the at

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least one region instead of the second material is changed. Also, it is unclear how the position of the structural elements change with respect to the second material, when the second material are part of the structural elements themselves. It also seems that the position of the second material (at least one region) changes, not the position of the structural elements. It seems applicant intended to claim the position of the at least one region to change relative the remainder of the structural elements, however is it unclear as currently claimed. Claims 69-76 depend upon claim 68 and inherit all problems associated with the claim.

Claim 72 recites, "the second material is configured to *measure* at least one physiological condition". It is unclear how a material "measures". It seems applicant intended to claim "respond to" as in comparable claim 81, instead of "measure".

Claim 77 is indefinite. Line 8 requires the second material to change positions. It is unclear how a material changes position. It seems applicant may have intended to claim the at least one region to change positions instead of the second material. It is also unclear how the first position is coplanar with the surface of the structural elements, when the second material are *part of* the structural elements? How can a part be positioned relative to itself? Claims 78-85 depend upon claim 77 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 68-69, 72, 74, 76, 77, 78, 81, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al. (US 2004/0260391 A1, cited previously) in view of Palmaz (US 4,733,665). Santini discloses an in vivo sensor device system (stent; seen in fig.9a-9c) substantially as claimed comprising a plurality of structural elements (individual struts of stent seen for example in fig.9a, other stent shapes disclosed P0095-P0098; P0064-P0067) defining the device, the structural elements (struts) composed of a first material (substrate) having a first transitional temperature and coefficient (inherent property of the substrate/stent material) and at least one region (caps) of the structural elements composed of a second material (cap material) having a transitional temperature and coefficient higher than the first material (different microchip caps made of different materials with different transitional temperatures or deform at different rates, P0030, P0048, P0046), allowing a change in geometry or conformation in the second diametric state (final configuration) upon application of a force (heat or pressure), wherein the change in geometry changes the position of the structural elements (struts) relative the second material (caps; caps move to different position angled away from strut surface, see figures 4a-4c for example; P0045) and a detection mechanism (console, monitoring system, P0090, P0091). Santini discloses the in vivo sensor substantially as claimed, however is silent to whether the stent is diametrically expandable or not between a first and second diametric state. Stents are well known in the art to radially expand in order to function properly to open and maintain open a vessel. Santini does not recite any expansion, however it would seem inherent that since vascular stents are disclosed, they must be expandable. If not inherent, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the stents of Santini to be expandable so as to be able to deliver them to the vasculature at a small

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diameter, minimizing trauma then enlarging to fully support the vessel wall. See as evidence Palmaz which shows several different known stent shapes that all expand to a larger diametric state to fully support the vessel.

Claims 68-72, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmeister (EP 0 759 730 B1, cited previously) in view of Wolinsky et al. (US 6,840,956 B1, cited previously). Regarding claim 68, Burmeister discloses an in vivo sensor device system (stent 10; seen in fig.1, 5, or 6) comprising a plurality of structural elements (individual struts, 12+14) defining the device, the structural elements (struts) composed of a first material (struts 12, 62, 52 made of an austenite material) having a first transitional temperature and coefficient to expand from a first diametric state (delivery state) to a second diametric state (self-expanded state; col.2, lines 16-19) and at least one region (struts 14, 54, and 64) of the structural elements composed of a second material (martensite superelastic material 34) having a transitional temperature and coefficient higher than the first material (see fig.4a, 4b showing transitional temperature greater for material 34; P0029, P0032), allowing a change in the geometry or conformation upon application of a force (balloon force; col.2, lines 20-23 causes geometry change after the self expansion), wherein the change in geometry changes the position of the structural elements (12, 62, 52) relative the geometry of the second material (14, 64, 54- these struts move radially outward towards the plane of the rest of the structural elements when forced outward by the balloon). Burmeister discloses the system substantially as claimed, however is silent to mention any detection mechanisms for measuring the geometry/conformation change of the second material (plastic final expansion) relative the

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structural elements (that have already been diametrically self expanded). Wolinsky teaches in the same field of stents (16; fig.2), the use of a detection mechanism (fluoroscopy; col.6, lines 12-15) in order to view the insertion, position and expansion of the stent to insure the stent was implanted correctly. Such imaging techniques are well known in the stent art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Burmeister's stent system with Wolinsky's teaching of using fluoroscopy (detection mechanism) with the implantation of stents, in order to provide a system that provides the surgeon with assistance and reassurance that the stent was positioned accurately in the vessel (as fluoroscopy views the stent during expansion, it also displays the structural elements/struts changing configuration).

Burmeister discloses the first material to comprise a shape memory material and the second material to comprise a superelastic material, wherein the second material has a higher martensite transition temperature (see fig.4b compared to fig.4a). Burmeister's second material (martensite struts) is configured to monitor a condition such as pressure (pressure is created by fluid flow or plaque build-up) or temperature (stent changes shape when expanded in response to pressure or temperature, P0030, P0032, P0012, thus is considered to measure these parameters).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738